

REMARKS

Claims 1, 3, 7-10, 18-38, 40, and 41 are pending, with claims 2, 4-6, 11-17, and 39 canceled and claims 19-31 withdrawn. Claim 3 has been amended to clarify the language. Claim 10 has been amended. Support for the amendment can be found at least in the original claim 10 and page 1, lines 24-28, page 9, lines 16-23, and page 17, line 45-page 18, line 5 of the Specification. Claims 37 and 38 have been canceled. Upon entry of this amendment, claims 1, 3, 7-10, 18, 32-36, 40, and 41 will be pending, with claims 19-31 withdrawn.

Rejections under 35 U.S.C. § 103(a) over Nobuko, Patel, Hoogendoorn, and Pellegrini

Claims 1, 3, 7-10, 18, 32-38, 40, and 41 stand rejected under 35 U.S.C. § 103(a) as allegedly rendered obvious over Japanese Patent Application Publication 09-249562 (“Nobuko”) in view of U.S. Patent No. 6,569,463 (“Patel”) and further in view of U.S. Patent No. 4,150,113 (“Hoogendoorn”) and U.S. Patent No. 6,455,557 (“Pellegrini”). Applicants respectfully traverse.

None of the references cited teach or suggest an acidulant in an amount to obtain saliva with a pH of 2 to 7, as recited in independent claim 1. Nobuko merely discloses formulations that have a $\text{pH} \leq 5.5$ when made into a 1% aqueous suspension (see paragraph [0007]-[0008] of the machine translation of Nobuko, attached herewith). On the other hand, in order to obtain saliva with a pH of 2 to 7, the amount of acidulant will depend on many factors such as the intended rate of release of the drug, the choice of acidulant, the rate at which it is released into the mouth, and the profundity of the patient’s salivation (see the first paragraph on page 11 of the Specification). Additionally, the pH of a patient’s saliva may also be affected by excipients that would not affect the pH when placed in an aqueous suspension but would affect the pH when placed in saliva because of the bacteria in saliva. Therefore, the pH range of the tizanidine formulations disclosed in Nobuko does not correlate with the recited saliva pH range, and it would not have been obvious for one of ordinary skill in the art to modify the formulations with the pH range disclosed in Nobuko to reach the fast dissolving tablet with an acidulant in an amount to obtain saliva with a pH of 2 to 7, as recited in claim 1.

The deficiency of Nobuko is not cured by Patel, Hoogendoorn, or Pellegrini because none of them, alone or in combination, teach or suggest a fast dissolving tablet with an acidulant in an amount to obtain saliva with a pH of 2 to 7 either. It would not have been

obvious for one of ordinary skill in the art to combine the cited references to reach the claimed invention.

For at least the reasons stated above, a *prima facie* case of obviousness has not been established. Withdrawal of the rejections is respectfully requested.

CONCLUSION

Applicants submit that the claims are allowable. An early and favorable action to that effect is respectfully requested.

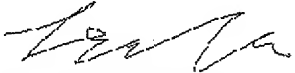
If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same.

No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 10-0600.

Respectfully submitted,
Kenyon & Kenyon LLP

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By:


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Enclosure:

Machine Translation of Japanese Patent Application Publication 09-249562
("Nobuko")